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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 419,927	10 18 1999	MARINUS BLAABJERG SORENSEN	MCG046US	2102

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PAUL GRANDINETTI
LEVY & GRANDINETTI
SUITE 1401
1725 K STREET NW
WASHINGTON, DC 200061401

EXAMINER

HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06.10.2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/419,927

Applicant(s)

SORENSEN, MARINUS
BLAABJERG

Examiner

Fozia M Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/11/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 10-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and 121.

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s)

6) ☐ Other

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DETAILED ACTION

1a. Receipt of Applicants' arguments and amendments filed in Paper No.18, filed on 11 March 2003 is acknowledged. Claims 1-9 have been canceled, and new claims 10-15 have been added.

1b. The title of the invention has been changed.

Response to Amendment:

2. *The following previous objections and rejections are withdrawn in light of Applicants amendment filed in Paper No 18, 03/11/03.*

(l) All of the rejections made against claims 4-9.

Claim Rejections:

Claim Rejections - 35 U.S.C. §112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3a. Claims 10-15 are rejected under 35 U.S.C. 112, first paragraph, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 10-15 of the instant invention are directed to a composition comprising an extensin and pectin or pectin polysaccharide, in a concentration sufficient to activate eukaryotic cells to survival, proliferation or survival and proliferation.

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The specification asserts that the claimed composition can be beneficial to health because it can enhance the activity of the immune system, (page 4, lines 23-26).

However, Applicants have not shown that the claimed composition enhances the immune system. Instant specification only discloses an oligo-cell experiments testing different pectins and combination of pectins and extensins in their ability to stimulate the proliferation of *Tetrahymena thermophila* cells (T- thermophila), (see page 12, lines 8-12). Applicants state that the similarities between T-thermophila cells and animal cells justifies the use of T. Thermophila cells as substitute for mammalian cells, (page 12, lines 11-20). Instant specification demonstrates that a combination of pectins and extensin increased cloning efficiencies of T-thermophila cells, and that partially purified extensin caused 80% cloning efficiency, (see page 13). However, instant specification does not demonstrate the claimed composition activates all eukaryotic cells to survival, proliferation or survival and proliferation.

There are no experiments or guidance provided showing that the claimed composition activates all eukaryotic cells to survival, proliferation or survival and proliferation, neither does the specification disclose the concentration of the claimed composition that is sufficient to activate eukaryotic cells to survival, proliferation or survival and proliferation.

The criteria set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount

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(4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue extermination. In the instant case, the quantity of experimentation to determine the ability of a composition comprising extensin and pectin or extensin and pectin polysaccharide, to activate the proliferation and survival of "all" eukaryotic cells, and to determine the concentration sufficient for said activation, would be enormous and would, therefore be undue.

Therefore, due to the lack of direction or guidance in the specification, the absence of working examples and teachings of the prior art, the unpredictability in the art, and the complex nature of the invention, undue experimentation would be required of the skilled artisan to use the claimed composition comprising extensin and pectin or extensin and pectin polysaccharide for the activation of the proliferation and survival of "all" eukaryotic cells. As such one of ordinary skill in the art would not know how to use the invention recited in instant claims 10-14.

Claim rejections-35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3a. Claim 10 recites " a composition comprising....., (1) at least one pectin, 2) at

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composition comprises: (1) an extensin and at least one pectin, or (2) an extensin and at least one "polysaccharide" found in pectin, and if so, which polysaccharide?. While it is clear the first component of the claimed composition is extensin, the identity of the second component is unclear.

3b. Regarding claim 10, the phrase "activate" renders the claim indefinite because it is unclear how the eukaryotic cells are activated? Does this mean that the cells are stimulated to proliferate? Does it mean that the cells are promoted to survive?

Clarification of the meaning of "activate" is requested.

3c. Claim 11 recites "... wherein the member is a pectin", which renders the claim indefinite, because it is unclear which member is being referred to. Does this mean that the second member of the composition of claim 10 is pectin?. Appropriate correction is required.

Claims 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite, so long as they depend on claims 11 and 10 for the limitations set forth directly above.

Conclusion

4. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
June 9, 2003

Gary L. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600